NBER WORKING PAPER SERIES

UNINTENDED CONSEQUENCES OF PRODUCTS LIABILITY: EVIDENCE FROM THE PHARMACEUTICAL MARKET

Eric Helland
Darius N. Lakdawalla
Anup Malani
Seth A. Seabury

Working Paper 20005 http://www.nber.org/papers/w20005

NATIONAL BUREAU OF ECONOMIC RESEARCH 1050 Massachusetts Avenue Cambridge, MA 02138 March 2014, Revised March 2018

The authors would like to thank Derek Neal and workshop participants at the American Law & Economics Association Meetings, the Conference on Empirical Legal Studies, Harvard Medical School, NBER Health Care Group Spring Meeting and Summer Institute, Rice University, UCLA, and the University of Chicago. Drs. Lakdawalla and Seabury thank the National Institute on Aging (1RC4AG039036 and 1P01AG033559) for financial support. Mr. Malani thanks the financial support of the Samuel J. Kersten Faculty Fund and the Microsoft Fund at the University of Chicago Law School. The views expressed herein are those of the authors and do not necessarily reflect the views of the National Bureau of Economic Research.

At least one co-author has disclosed a financial relationship of potential relevance for this research. Further information is available online at http://www.nber.org/papers/w20005.ack

NBER working papers are circulated for discussion and comment purposes. They have not been peer-reviewed or been subject to the review by the NBER Board of Directors that accompanies official NBER publications.

© 2014 by Eric Helland, Darius N. Lakdawalla, Anup Malani, and Seth A. Seabury. All rights reserved. Short sections of text, not to exceed two paragraphs, may be quoted without explicit permission provided that full credit, including © notice, is given to the source.

Unintended Consequences of Products Liability: Evidence from the Pharmaceutical Market Eric Helland, Darius N. Lakdawalla, Anup Malani, and Seth A. Seabury NBER Working Paper No. 20005
March 2014, Revised March 2018
JEL No. H7,I1,I11,K13

ABSTRACT

In a complex economy, production is vertical and crosses jurisdictional lines. Goods are often produced by a global or national firm upstream and improved or distributed by local firms downstream. In this context, heightened products liability may have unintended consequences for consumer safety. Conventional wisdom holds that an increase in tort liability on the upstream firm will encourage that firm to improve safety for consumers. However, in the real-world, policy actions in a single jurisdiction may not be significant enough to influence the behavior of an upstream firm that produces for many jurisdictions. Even worse, if liability is shared between upstream and downstream firms, higher upstream liability may decrease the liability of the downstream distributor and encourage it to behave more recklessly. In this manner, higher upstream liability may perversely increase the sales of a risky good. We demonstrate this phenomenon in the context of the pharmaceutical market. We show that higher products liability on upstream pharmaceutical manufacturers reduces the liability faced by downstream doctors, who respond by prescribing more drugs than before.

Eric Helland
Claremont McKenna College
Department of Economics
Claremont, CA 91711
eric.helland@claremontmckenna.edu

Darius N. Lakdawalla University of Southern California 635 Downey Way, VPD 414-K Schaeffer Center for Health Policy and Economics Los Angeles, CA 90089-7273 and NBER dlakdawa@usc.edu Anup Malani University of Chicago Law School 1111 E. 60th Street Chicago, IL 60637 and NBER amalani@uchicago.edu

Seth A. Seabury
Schaeffer Center for Health Policy
and Economics
University of Southern California
635 Downey Way
VPD 414C
Los Angeles, CA 90089
and NBER
seabury@usc.edu

A common feature of modern, complex economies is vertical production that crosses jurisdictional lines. Upstream firms supply inputs for downstream firms who add value and sell to consumers. Firms at all levels have grown in scale and scope, and they now often serve many markets across a range of different jurisdictions. This geographic expansion is perhaps even more pronounced for upstream firms, because downstream firms, such as distributors and retailers, often need to retain a well-defined local presence.

To remain effective, the legal regime must carefully account for the value and risk added by each firm in the vertical chain of production. To some extent, tort law has adapted. For example, in the 19th century, a doctrine called "privity" prevented individuals from suing upstream firms for injuries from products of downstream firms. However, cases such as *MacPherson v. Buick Motor Company* (N.Y. 1916) and *Smith v. Peerless Glass Co* (N.Y. 1932) abandoned the doctrine of privity and allowed consumers to sue firms further upstream (Prosser 1960). Indeed, contemporary products litigation is now characterized by suits against several firms in the vertical chain of production. It is also economically significant. Overall torts liability grew four times faster than the overall economic growth rate between 1930 and 1994 (Sturgis 1995). By 2009, total payments in products liability suits alone amounted to \$248.1 billion, or 1.74% of U.S. GDP (Towers Watson 2010). In health care, suits against doctors amount to 1-2% of physician expenditures (Mello, Chandra et al. 2010), and suits against drug companies amount to 2.26% of all drug expenditures.²

However, in other ways, US tort law has lagged the modern economy, especially in its insistence upon state, rather than national or global, tort rules. This has encouraged beggar-thy-neighbor policies by states who have incentives to shift liability from local downstream defendants to upstream national defendants lacking a local presence (Krauss 2002). For instance, 22 states have reduced the products liability local retailers face but not the liability that upstream manufacturers face (Shepherd 2012). Nearly 30 states have caps on total or non-economic damages that physicians face in medical malpractice actions. In litigation involving injuries from prescription drugs or devices, these caps shift liability from local doctors to upstream national medical products and drug companies. While the legal

.

¹ For example, plaintiffs sue both the manufacturer of the car whose tire burst and the manufacturer of the tire (e.g., *In re Bridgestone/Firestone, Inc.*, S.D. Ind. 2003), the home builder that used contaminated materials and the maker of those materials (e.g., *In re Chinese Manufactured Drywall Products*, E.D. La. 2010), the grocer that used spoiled food and the company that supplied the grocer with the spoiled food (e.g., cases against retailers and farmers implicated in the 2006 E. coli outbreak), and the doctor that prescribed a drug as well as the company that produced it (e.g., *Wyeth v. Levine*, U.S. 2009) This last example is also the topic of the empirical application in this paper.

This estimate is derived from all settlement special items reported in the income statement. For pharmaceutical companies this represents provisions to alter reserves for litigation and settlement. For other companies the amount would include insurance payments from the firms general liability policy but pharmaceutical firms do not typically have insurance against loses in litigation. As such the sum of the settlement special items represents unexpected payments in litigation. Although some of this litigation is likely not related to product liability the vast majority of loses in excess of reserves is likely major product liability cases—a fact reflected by disclosures in the 10k statements. We sum the total special reserves incurred from 2002-2008 and divide this by total sales over the same period to get the ratio of 2.26%.

system recognizes the multiple-jurisdiction problem, the strategies employed for addressing it are widely viewed as inadequate.³

The economics literature on tort liability and products regulation has neglected the implications of vertical production for tort rules. The majority of the literature assumes a single producer (Spence 1977; Polinsky and Rogerson 1983; Landes and Posner 1985). The economics literature on joint and several liability does tackle the problem of multiple tortfeasors (Landes and Posner 1980; Sykes 1984; Kornhauser and Revesz 1989; Miceli and Segerson 1991; Kornhauser and Revesz 1994; Currie and MacLeod 2008). However, it typically abstracts from the contracting between upstream and downstream firms that is central to vertical production. A partial exception is Hay and Spier (2005), which discusses optimal allocation of tort liability between a producer and a consumer when the consumer's use of a product may injure third parties. However, Hay and Spier, like the articles cited in the prior paragraph, assume that all actors operate in one jurisdiction. Moreover, their model assumes the consumer (or, by analogy, the downstream firm) can contract on quality. This strong assumption contrasts with the large literature on incomplete contracts (Bolton and Dewatripont 2005).

In this paper we present and empirically test a model of products liability that studies the implications of both vertical and multi-jurisdictional production. The upstream firm in our model

.

One such strategy is the use of model codes and restatements of law that are meant to harmonize laws across states. However, these uniformity movements tend to stop at the national border, and they often have patchy adoption across states. For example, about half the states have punitive damages caps and less than two-third have reformed joint and several liability Malani, A. and J. Reif (2013). Interpreting Pre-trends as Anticipation: Impact on Estimated Treatment Effects from Tort Reform.. The second device is the class action suit. Yet the hurdles to meet class action status remain high. The threshold for certification is even higher if the class involves residents from multiple states. For example, a prior study on a sample of lawsuits shows that 82% of class actions involved residents of a single state Pace, N. M., S. J. Carroll, et al. (2007). Insurance class actions in the United States. Santa Monica, CA, RAND Corporation.. Moreover, these suits have been criticized as resulting in settlements that benefit producers and plaintiffs' attorneys at the expense of plaintiffs Hensler, D. R. (2000). Class action dilemmas: Pursuing public goals for private gain, Rand Corporation.. The last is national regulation of safety. These regulations are porous and leave a large role for state tort actions (e.g., Wyeth v. Levine, U.S., 2009). Further, the legal system tends to disfavor preemption of state suits by federal regulation, so product liability still varies across states Schwartz, V. E. and C. Silverman (2009). "Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety." Tul. L. Rev. 84: 1203..

⁴ This modeling choice contrasts, for example, with the economic literatures on tax and regulatory competition, which assumes that legal rules vary across jurisdictions and that firms can operate in multiple jurisdictions and can change jurisdictions to avoid regulation Oates, W. E. and R. M. Schwab (1988). "Economic competition among jurisdictions: efficiency enhancing or distortion inducing?" <u>Journal of public economics</u> **35**(3): 333-354.. The regulatory competition literature does not address the exact analogue of the case we consider here: the effect of a single jurisdiction's liability rules when firms operate in that and other jurisdictions.

⁵ This contracting has an important effect on welfare: it may be possible by allocating liability asymmetrically among tortfeasors to achieve the first best. This is similar the insight that contracting between agents can address moral hazard in teams without a budget breaker Legros, P. and S. A. Matthews (1993). "Efficient and Nearly-Efficient Partnerships." The Review of Economic Studies **60**(3): 599-611..

operates in multiple jurisdictions.⁶ Tort rules allocate liability between upstream and downstream firms. And, in many cases, increases in upstream liability reduce the liability flowing downstream, and viceversa. We assume that consumers cannot contract over product safety, so that products liability can theoretically improve welfare. We also assume that the downstream firm cannot contract with the upstream firm over safety, a second contrast with Hay and Spier.⁷ Downstream firms do, however, contract over quantity, i.e., purchase from the upstream firm, distinguishing our model from the prior literature on multiple tortfeasors.

The central implication of our model is that, when upstream firms operate in multiple jurisdictions, efforts by a local jurisdiction to impose greater liability on upstream firms may increase output of the hazardous good, a result that runs contrary to all prior models of tort liability. Because the upstream firm operates in multiple jurisdictions, its nationwide precautionary behavior – and thus its supply function – does not change dramatically in response to local tort reforms. However, since higher upstream liability often reduces the share of liability that flows downstream, the local downstream distributor's demand for the hazardous upstream product increases. The perverse result is higher equilibrium output of the risky good in a local jurisdiction that imposes stricter tort liability upstream. Product liability imposed on the upstream firm functions as a type of insurance for the downstream firm. The result is analogous to moral hazard, as the downstream firm produces more of the hazardous good in light of its extra insurance.

From a normative point of view, the presence of multiple jurisdictions undermines the typical welfare logic of tort rules. With a single, uniform legal regime, the upstream firm passes on its liability costs to the downstream firm in the form of its price. This "pass-through" liability cost plus the downstream firm's own direct liability cost ends up being exactly equal to the total liability associated with the product. In this case, the downstream firm faces exactly the right incentives, and efficiency ensues. However, this logic breaks down when the upstream firm operates in multiple jurisdictions.

With multiple jurisdictions, the upstream firm's liability costs are equal to the market-weighted average liability cost across all jurisdictions. It continues to transmit these costs downstream in its pricing, but in this case, the "pass-through" cost plus the downstream firm's local liability cost may not add up to the true liability in each locale. With multiple jurisdictions, incentives are aligned only in those

⁶ Upstream and downstream firms are assumed to be competitive. The results remain, modulo double marginalization, if the firms have market power Polinsky, A. M. and W. P. Rogerson (1983). "Products Liability, Consumer Misperceptions, and Market Power." <u>The Bell Journal of Economics</u> **14**(2): 581-589..

In contrast to Spence Spence, M. (1977). "Consumer misperceptions, product failure and producer liability." <u>The Review of Economic Studies</u> **44**(3): 561-572., we assume consumers do not underestimate (or overestimate) risk, so that mistaken beliefs do not drive inefficiency in our model.

⁸ Prior models of tort assume tort liability increases supply costs ibid, Polinsky, A. M. and W. P. Rogerson (1983). "Products Liability, Consumer Misperceptions, and Market Power." The Bell Journal of Economics 14(2): 581-589, Landes, W. M. and R. A. Posner (1985). "A Positive Economic Analysis of Products Liability." The Journal of Legal Studies 14(3): 535-567. In a prior working paper, however, we show that, if there are transactions costs, higher tort liability can increase demand and thereby increase equilibrium supply, but, unlike in the current paper, there we did not consider the relationship between upstream and downstream liability.

jurisdictions where the upstream liability rule is exactly equal to the average liability imposed by all jurisdictions together. States imposing above average upstream liability costs will suffer excessive output of the risky good, because downstream firms will behave too recklessly. In these states, further increases in upstream liability exacerbate the inefficiency and lead to even more sales of the risky good, and vice-versa.

We use punitive damage caps to measure liability on upstream pharmaceutical firms. We show that an increase in upstream punitive damage liability on drug companies lowers the absolute level of liability faced by downstream doctors. We then find that higher upstream drug liability leads to an increase in prescribing by downstream doctors. However, in states where noneconomic damage caps already limit liability for doctors, we find that changing the liability of upstream firms does not affect prescribing by downstream doctors.

Table 1 provides a simple illustration of our main empirical findings. The table reports average drug sales—measured as the number of prescriptions written per outpatient visit—by state according to the products liability and malpractice liability regimes. Surprisingly, states with higher products liability for upstream drug manufacturers have 2.3% more drug prescriptions per visit as compared to states with lower liability exposure for manufacturers.

Closer inspection reveals that this increase is driven by the subset of states where liability is shared across doctors and drug companies, rather than by the states in which liability is targeted exclusively at drug companies themselves. States that cap malpractice liability for physicians are effectively shifting all, or nearly all of, the liability upstream, without sharing it across the vertical chain of production. Thus, increases in upstream liability have no spillover effects on the liability faced by downstream firms. In these states, higher upstream liability has the expected effect of reducing prescribing by 5.2%. However, among states without caps where liability is shared between drug companies and doctors, greater upstream liability leads to a 7.4% increase in prescription drug utilization. While these results are unadjusted for other factors, we obtain qualitatively similar findings even with a full set of regression controls and various fixed effects specifications.

This result stands in stark contrast with the prior empirical literature on tort liability. A number of studies find that higher tort liability reduces quantity of output in health care, at least as measured by the supply of physicians or physician services (Kessler, Sage et al. 2005; Klick and Stratmann 2007; Matsa 2007; Currie and MacLeod 2008; Helland and Showalter 2009; Helland and Tabarrok 2012; Malani and Reif 2013). In general, no prior studies find that higher liability is associated with increased output, though there is much recent evidence that the threat of malpractice liability does change physician

4

.

⁹ One concern is that higher permissible punitive damages do not merely shift liability from downstream doctors to upstream drug companies, but rather increase liability of both actors. Punitive damages are easier to obtain, however, if the doctor testifies against the drug company. Thus plaintiffs frequently give doctors a break on liability in order to increase the expected punitive award from drug companies. Moreover, doctors rarely pay punitive damages.

 $[\]overset{1}{}^{10}$ The data and methods used to construct the table are described in detail in Section II.

treatment patterns (Cotet 2012; Frakes 2012; Frakes 2013; Avraham and Schanzenbach 2015). Moreover, no papers find (or explain) that the effect of higher liability on upstream firms depends on the liability of downstream firms. We find that the spillover effects of liability on upstream firms on downstream firms are an empirically significant phenomenon, at least in the pharmaceutical industry.

The remainder of the paper can be outlined as follows. Section I presents models of tort liability with vertical production and an upstream firm that operates in multiple jurisdictions. Section II presents our empirical application. We conclude with topics for future research.

I. Theory

A. Economic environment

We begin with an upstream firm that produces a hazardous input that it sells to downstream firms in *N* different legal jurisdictions. For simplicity, each downstream firm operates in only one market or jurisdiction. The latter assumption does not sacrifice generality so long as downstream firms can set retail prices differentially across jurisdictions in order to reflect different levels of liability risk.

The amount of hazardous input sold in jurisdiction i is denoted x_i . Each representative firm in jurisdiction i produces an output $y_i = f(x_i)$, which is sold at the price p_i . Downstream production is increasing and concave ($f_x > 0$, $f_{xx} < 0$). The hazardous input has marginal cost of production c and associated input price w.

We make two simplifying assumptions here that are relaxed in the appendix. First, to focus on the most relevant aspects of the problem, we assume production depends only on the risky input, not on any safe inputs. Second, to abstract from welfare costs due to market power, we assume upstream and downstream firms are competitive.

The upstream hazardous good producer may have various tools at its disposal for managing harms, depending on the nature of the good being produced. Some manufacturers may be able to make direct safety investments in production that reduce risk – for instance, firms producing consumer goods like clothing and tires. Others may be unable to influence the actual safety of the good, but able to warn users about the product's risks. Pharmaceuticals are a prime example. U.S. tort law addresses the first situation in "design defect" and "manufacturing defect cases" and the second in "failure to warn" cases.

The product in our empirical application – pharmaceutical drugs – is legally exempted from design defect liability. Courts have concluded that drugs are inherently unsafe and hold pharmaceutical companies liable only for failure to disclose known side effects to physicians.¹² Therefore, we present a

5

¹¹ We consider the allocation of liability between an upstream and downstream firm. However, the model can be extended to the case of a single producer and a consumer, where the consumer's use of the product can harm third parties, as in Hay and Spier Hay, B. and K. E. Spier (2005). "Manufacturer Liability for Harms Caused by Consumers to Others." <u>The American Economic Review</u> **95**(5): 1700-1711..

¹² See Restatement (Second) of Torts §402a, cmt. K.

model in which the upstream firm can only warn users about product risks. The appendix analyzes a model of an upstream firm that can also change the safety of its products.

The harm to consumers in jurisdiction i from the hazardous input is proportional to its utilization in the final product according to hx_i , where h is a fixed factor beyond the upstream firm's control. Conceptually, h is the summation of different risks associated with the input. For example, it could be the sum total of harms in the aviation industry associated with aircraft engine failure, body failure, electronics failure, and so on. The upstream firm can choose to report some of these harms, but not others. To capture this, we let the upstream firm choose to report the share r of these harms.

We make three critical assumptions that govern the harm from the hazardous input. First, we assume the upstream firm sells a common product across jurisdictions, so it cannot customize warnings by jurisdiction. In a national or global marketplace, arbitrage forces the upstream firm to sell at a common price across jurisdictions. If upstream firms can easily price discriminate across jurisdictions, the multiple jurisdiction problem collapses to the single-jurisdiction model, which behaves in a more standard fashion. However, this price-discrimination is often difficult to achieve, particularly across state lines within the US.

Second, we assume that, while the upstream firm knows the harm from its product, the downstream firm does not. It must infer harm from the tort environment and any disclosures that the upstream firm makes.

Third, we assume that demand for the final output does not depend on the harm hx_i . This is a common assumption in the literature on products liability. The typical justification is that, if the assumption failed to be true, consumers would be able to observe and contract directly for the level of safety they desire, without products liability rules (Miceli 1997). This type of contracting or demand behavior is not typically seen, either because safety is not observable at the time of contracting, or because it is costly to negotiate a settlement after the safety of the product is revealed through use. Another possible justification is that consumers have health, life, or property insurance that makes them indifferent to the harm. Each of these justifications appears plausible in the pharmaceutical industry, which is the subject of our empirical application.

1

 $^{^{13}}$ We abstract from dynamic decisions relating to product withdrawal and introduction.

There may be a role where consumers demand heterogeneous levels of safety but there is only one (upstream) producer and it can only supply one level of safety. For example, Choi and Spier Choi, A. H. and K. E. Spier (2014). "Should Consumers be Permitted to Waive Products Liability? Product Safety, Private Contracts, and Adverse Selection." Journal of Law, Economics, and Organization 30(4): 734-766. Consider the case where safety depends on precautions by a single producer and consumers differ in the probability of being harmed by a product. The firm may choose to lower its precaution in order to select for lower risk consumers much as insurance companies may reduce coverage on a given policy in order to adversely select for lower risk beneficiaries. Non-waivable products liability, like an insurance mandate, stops this selection. Note that the sale of multiple products with different levels of safety and price, as in Hay and Spier Hay, B. and K. E. Spier (2005). "Manufacturer Liability for Harms Caused by Consumers to Others." The American Economic Review 95(5): 1700-1711., can do the same, though it reduces cross subsidization.

The total damages awarded by courts in jurisdiction i are given by hx_i . Whereas final consumers cannot easily observe product safety, courts – through evidentiary discovery – are able to both observe and punish lapses in safety. This too is a common assumption in the literature on products liability. The amount of total damages captures the legal restriction that damages cannot generally exceed the losses suffered by consumers. 15 A critical issue in our context is how the total liability is shared across upstream and downstream firms. We assume this depends on two parameters. First, the upstream firm can protect itself by disclosing more harms. Therefore, the upstream firm's share of liability falls with r, the share of harms disclosed. Second, the policy regime might influence the allocation of liability across upstream and downstream firms. For example, in the pharmaceutical context, state laws protecting downstream physicians from large tort claims might reduce the share of liability that flows downstream, and vice-versa. Therefore, we express the upstream firm's share of damages in jurisdiction i as $a_i = a(t_i, r)$, which depends on some tort policy parameter, $t_i \in [0,1]$, and the rate of disclosure. Note that tort law may vary across jurisdictions, but a firm's disclosure is constrained to be the same across jurisdictions, because information travels freely. We assume upstream share of liability rises in the tort parameter, i.e., $a_{it} > 0$. Moreover, we assume that the upstream firm's share of liability a is decreasing in the share of harms it discloses: $a_r < 0$. We also assume disclosure, if anything, relieves greater tort liability the higher is that tort liability, i.e., $a_{tr} \leq 0$.

We do not explicitly model the disclosure game that upstream and downstream firms play, and thus the inferences that the downstream firm draws from an upstream firm's disclosure signal. A specific disclosure game would limit the generality of the analysis. Instead, in order to keep the analysis simple and at a price-theoretic level, we make two assumptions. First, we presume that the upstream firm fails to disclose all the hazards associated with its product. As we show later, this assumption implies that downstream firms will believe a good is riskier whenever the upstream firm discloses more harms. Second, we assume that, whatever game firms play, downstream firms update their beliefs about product hazards purely on the basis of upstream firm disclosures, and not the tort law regime per se. In other words, $E[h|t',rh] = E[h|t'',rh] \forall t',t''$, where E[h|t,rh] reflects the downstream firm's inference about the hazards of the upstream output given tort law and upstream disclosure. While this assumption rules out complex effects of the policy configuration on beliefs, it captures the fairly intuitive first-order effects of disclosure.

B. Liability rules, behavior, and welfare

The upstream firm embeds its expected liability costs in the price that it transmits downstream. We first show how liability rules mediate the relationship between liability costs and pricing.

Upstream firm. The upstream firm's objective is

$$\max_{r} \Sigma_{j} x_{j}(r) (w - c - a(t_{j}, r)h)$$

-

¹⁵ An exception is punitive damages, a topic we will take up in the empirical section.

When upstream profits are zero due to competition, the optimal price w passes on the average upstream tort liability: $w=c+\bar{a}h$, where $\bar{a}=\Sigma_j a(t_j,r)x_j(r)$ is the sales-weighted average of the upstream firm's liability allocation across jurisdictions. The firm's optimal disclosure policy r^{**} balances the reduction in demand against the reduction in average tort costs. However, policy changes within a single jurisdiction have much smaller effects than analogous changes that apply globally. To see this, observe that:

$$\frac{\partial r^{**}}{\partial t_i} = \frac{-x_i' a_{i,t} h - x_i a_{i,rt} h}{-SOC} > 0, \forall i$$

The SOC term in the denominator is the second derivative of the objective function and is thus negative. This effect of jurisdiction i's tort law on disclosure is always positive, as are the corresponding effects of each independent jurisdiction j. Therefore, it follows that adding up the effects of tort changes across the individual jurisdictions will magnify the total effect on disclosure, or that:

$$\frac{\partial r^{**}}{\partial t_i} = \frac{-x_i' a_{i,t} h - x_i a_{i,rt} h}{-SOC} < \Sigma_j \frac{\partial r^{**}}{\partial t_j}, \tag{1}$$

where SOC < 0 is now the upstream firm's second order condition in the heterogeneous legal environment. In the limit, as the share of jurisdiction i in total output goes to zero, an increase in upstream liability will have no effect on disclosure. In contrast, when legal regimes are homogeneous and policy changes occur in lockstep across jurisdictions, changes in liability rules always affect disclosure behavior.

Downstream firm. The downstream firm's objective is

$$\max_{x_i} p_i f(x_i) - (w + E[(1 - a(t_i, r^{**}))h|r^{**}h])x_i$$

After plugging in the upstream firm's prices into the first-order condition from this problem, the optimal input usage for the downstream firm satisfies:

$$pf_{x_i} = c + E[\bar{a}h|r^{**}h] + E[(1 - a_i)h|r^{**}h]$$

Note the effect of heterogeneous legal rules on this expression. If all jurisdictions move in lockstep, then $\bar{a}=a_i$, and this expression collapses to $pf_{x_i}=c+E(h|r^{**}h)$. Here, tort rules have no effect on downstream firm behavior, because the input price charged by the upstream firm perfectly embeds the cost of liability borne by the upstream firm. From a normative point of view, efficiency obtains in this case so long as tort policies induce downstream firms to make accurate inferences about harm, or that $E(h|r^{**}h)=h$.

¹⁶ Since disclosure r is bounded in [0,1], we know that the change in $\Sigma_j \partial r^{**}/\partial t_j$ must also be bounded. As $\Sigma_{\neg i} x_j \to \infty$, the ratio of $\partial r^{**}/\partial t_j$ to $\Sigma_j \partial r^{**}/\partial t_j$ must go to zero for (1) to hold.

If instead jurisdictions vary in their tort rules, the incentives of the downstream firm depart from efficiency even if they have accurate beliefs. Downstream firms typically face private liability costs that are higher or lower than social costs; perfect equality is a knife-edge case. Specifically, within jurisdictions where the local upstream share of liability is lower than average, the downstream firm will overutilize the input, relative to the efficient level.

Comparative statics imply that increasing upstream liability share affects output as follows:

$$\frac{\partial x}{\partial t_i} = \frac{1}{p f_{xx}} \left[\left\{ \left(\frac{\partial \bar{a}}{\partial t_i} - \frac{\partial a_i}{\partial t_i} \right) + \left(\frac{\partial \bar{a}}{\partial r^{**}} - \frac{\partial a_i}{\partial r^{**}} \right) \frac{\partial r^{**}}{\partial t_i} \right\} E[h|r^{**}h] + \left(\bar{a} + (1 - a_i) \right) \frac{\partial E[h|r^{**}h]}{\partial r^{**}} \frac{\partial r^{**}}{\partial t_i} \right]$$

When legal regimes are homogeneous, the above expression is negative, and imposing greater liability upstream results in less production of the risky good. However, for heterogeneous legal regimes, the sign of the above effect is uncertain. While additional tort liability in jurisdiction i has positive direct effects on upstream liability $(\partial \bar{a}/\partial t_i > 0)$, this effect is offset by greater disclosure $((\partial a_i/\partial r^{**})(\partial r^{**}/\partial t_i))$.

In the limit, as the upstream firm operates in more and more jurisdictions beyond i, the effect becomes clearer. As $X = \Sigma_{\neg i} x_j \to \infty$, the effect of a single jurisdiction's actions on average liability goes to zero, so that $\lim_{X\to\infty} \partial \bar{a}/\partial t_i = 0$. At the same time, the effect of a single jurisdiction's tort rules on the upstream firm's disclosure decision also goes to zero, so that $\lim_{X\to\infty} \partial r^{**}/\partial t_i = 0$. For this limiting case, higher upstream liability in jurisdiction i results perversely in greater use of the hazardous input:

$$\frac{\partial x}{\partial t_i} = \frac{1}{p f_{rr}} \left(-\frac{\partial a_i}{\partial t_i} E[h|r^{**}h] \right) > 0$$

When a single jurisdiction imposes more liability on the upstream firm, it fails to affect its behavior, because it is too small to do so. However, it does encourage its own local downstream firms to behave more recklessly, because they face less liability risk.

The following two propositions summarize the positive and normative implications of this analysis, respectively.

Proposition 1. Suppose the upstream firm cannot affect the safety of a product, the upstream firm has chosen an interior value for disclosure, and the downstream firm has chosen interior values for the hazardous input.

- A) In a homogenous legal environment, a global increase in upstream liability share will reduce downstream usage of the hazardous input, and its associated output.
- B) In a heterogeneous legal environment, an increase in upstream liability share within one jurisdiction has effects that are in general ambiguous.
- C) In a heterogeneous legal environment where the share of each jurisdiction in aggregate output goes to zero, an increase in upstream liability share within one jurisdiction will increase the use of the hazardous input in that jurisdiction.

Therefore, when legal regimes are homogeneous, imposing greater liability on upstream firms has the intended effect. Under heterogeneity, however, greater liability on upstream firms may perversely increase the use of the hazardous input, especially when each individual jurisdiction makes up a comparatively small share of output.

From a normative point of view, efficiency requires that downstream firms make accurate inferences about harms, and that upstream pricing appropriately embeds liability risk. The following proposition summarizes these findings.

Proposition 2. Suppose the upstream firm cannot affect the safety of a product, the upstream firm has chosen an interior value for disclosure, and the downstream firm has chosen interior values for the hazardous input.

- A) In a homogeneous legal environment, the first best is achieved if the tort parameter causes the downstream firm to make correct inferences about the harms of the hazardous input.
- B) In a heterogeneous legal environment, the first best is achieved if: (1) the tort parameter causes the downstream firm to make correct inferences about the harms of the hazardous input; and (2) the upstream share of liability within a jurisdiction is equal to the average share of upstream liability across all jurisdictions.
- C) In a heterogeneous legal environment where downstream firms make correct inferences about harms: (1) If the tort law parameters cause upstream share in jurisdiction i to be greater (less) than average upstream share, then the downstream firm will use more (less) of the hazardous input x_i and produce more (less) output y_i than is socially optimal; and (2) as the output share of jurisdiction i falls to zero, a change in tort law that causes upstream share to rise in jurisdiction i with above average upstream liability share a_i will reduce (increase) both welfare in jurisdiction i and global welfare.

The claim in Proposition 2C is proven in the appendix, but the intuition is straightforward. Jurisdictions with higher than average upstream liability are encouraging inefficiently reckless behavior by downstream firms. In such jurisdictions, further increases in upstream liability exacerbate this inefficiency and make the jurisdiction worse off.

II. Empirical analysis

A. Empirical predictions

Proposition 1 implies a number of testable predictions for the real-world case in which individual jurisdictions have small or minimal effects on global or national output.

1. Policy changes within a single jurisdiction will affect neither the liability exposure nor the disclosure behavior of the upstream firm, or $\frac{\partial \bar{a}}{\partial t_i} = 0$, $\frac{\partial r^{**}}{\partial t_i} = 0$. Therefore, tort rules that increase the liability faced by the downstream firm will lead unambiguously to less output in a jurisdiction, i.e., $\frac{\partial x_i}{\partial t_i} dt_i <$, if $dt_i < 0$.

- 2. Within a single jurisdiction, tort rules that increase the upstream share of liability perversely lead to more output in that jurisdiction, i.e., $\frac{\partial x_i}{\partial t_i} dt_i > 0$, when $\lim_{X \to \infty} \partial \bar{a} / \partial t_i = 0$, $\lim_{X \to \infty} \partial r^{**} / \partial t_i = 0$, and $dt_i > 0$.
- 3. As a corollary of #2, tort policy changes will not affect output if downstream firms are insulated from liability changes, $\frac{\partial x_i}{\partial t_i} dt_i = 0$, when $\frac{\partial a_i}{\partial t_i} = 0$, $\lim_{X \to \infty} \partial \bar{a} / \partial t_i = 0$, $\lim_{X \to \infty} \partial r^{**} / \partial t_i = 0$, and $dt_i > 0$.

Notice that effects 2 and 3 imply that the positive impact of upstream liability on output should be larger when downstream firms share liability than when they do not. Thus, the interaction effect between higher upstream liability and the imposition of liability for downstream firms should be *positive*. This is the empirical prediction generated by the theoretical model, and which we test in our empirical analysis.

We study the empirical context of state-level tort rules applied to the pharmaceutical market in the US. The pharmaceutical market is a useful setting in which to test our model, because it is populated by upstream drug manufacturers that produce drugs and downstream physicians' practices that use drugs as an input in the delivery of health care. Upstream drug manufacturers operate in multiple jurisdictions with different legal environments, which in our application are US states. In contrast, each downstream physician operates in only one state due to state licensing laws. Due partly to arbitrage opportunities and partly to the institutional detail that a small number of pharmacy benefit managers negotiate drug prices for most insurance plans, upstream drug companies sell any given drug at the same price across states and cannot fully control the quantity of sales within each state (Lakdawalla and Yin 2013). Downstream doctors can control sales within a state because, other than over-the-counter medications, drugs cannot be dispensed without a prescription. Finally, while branded drug manufacturers are not competitive, the Appendix demonstrates how our results generalize with a monopolist firm upstream. Positive and normative results are similar, holding fixed the standard deadweight loss from monopoly.

One difference between the pharmaceutical market in practice and the theory is the possibility that physicians may not internalize the full financial cost of drugs. In some cases they do, such as for physician-administered products, where traditionally physicians purchase drugs and then administer them in exchange for some reimbursement per unit administered (Polite, Conti et al. 2015). In other cases, they will internalize prices only partially, whether through altruism for the well-being of a patient that faces costs of taking a drug (Godager and Wiesen 2013), or through insurance companies that impose prior authorization or other costly compliance procedures on physicians before they can prescribe expensive products (LaPensee 2003). Mispricing will thus lead to overutilization through a different channel. Our theoretical results continue to apply, however, provided we compare them to a "second-best" equilibrium in which the only market failure is the underpricing of drugs to physicians.

We use the presence of punitive damage caps on products liability awards as the policy variable that increases the liability of upstream drug manufacturers relative to downstream physicians. We use the presence of a noneconomic damage cap on medical malpractice awards as the policy variable that

imposes liability on downstream physicians. Later, we explain how these policy parameters have the necessary effects on the allocation of liability upstream and downstream.

We begin by describing the various sources of data we use, in Section B. Section C provides background on products liability for pharmaceutical manufacturers, and then provides evidence that punitive damage caps shift liability from upstream drug manufacturers to downstream physicians, and vice-versa. Section D presents and tests some basic assumptions of our identification strategy, and discusses our empirical specification for the tests of the model. Section E presents our results.

B. Data

1. Quantity of drug sales

There is no single, nationally representative source for drug utilization data. We derive measures of the utilization of prescription drugs from a large database of private-sector health insurance claims. These data are drawn from the Touchstone database of Optum, a healthcare consulting firm. We received information on all pharmacy spending and utilization for all covered patients from 1997 to 2007. These data have been used in a number of prior analyses of pharmaceutical drug utilization (Joyce, Escarce et al. 2002; Goldman, Joyce et al. 2004; Goldman, Joyce et al. 2006).

Using these data, we construct aggregate measures of utilization by drug, state and year. While the Touchstone data track national numbers reasonably well, they are not designed to be a nationally representative sample. To address possible differences in sampling by state over time, we reweight the utilization data so as to be nationally representative by gender and age category. We begin by calculating state-level enrollment in Touchstone by gender, and 8 age categories (0-10, 11-19, 20-29, 30-39, 40-49, 50-59, 60-64, 65+). Next, we use the Current Population Survey (CPS) to calculate total US insured population by state, gender, and age cells. The CPS data are used to weight the Touchstone data and construct total utilization at the drug-state-year level. To normalize prescribing behavior according to population size and utilization of health care, we focus on the number of prescriptions for each drug per 1,000 total outpatient physician visits in a state and year.

2. Tort liability rules

Our identification strategy relies on legislative changes that impact expected tort liability separately for upstream manufacturers and downstream doctors. Our primary treatment variable for manufacturer liability comes from caps on punitive damages. Later we argue that these caps affect the share of upstream liability relative to downstream liability. We proxy for expected punitive damages liability using a variable that is set to zero if a state caps punitive damages and one otherwise. Thus we

-

¹⁷ The insured population includes individuals covered by private insurance or Medicare. We include Medicare because may of the old insureds in the MIDas data have both private coverage and Medicare.

¹⁸ Note that not every prescription requires a visit to a physician. Some prescriptions could be written at hospitals or in emergency departments. Also, we focus on 30-day equivalent prescriptions, so any refills count as separate physicians. So this measure should not be interpreted as the probability that a prescription is filled conditional on a visit.

interpret our treatment variable as legislation that creates high products liability within a state. Similarly, we use noneconomic damage caps as shocks to the medical malpractice liability of doctors. Our treatment variable for downstream doctor liability is set to zero if a state has a damage cap in place and one otherwise; it can be interpreted as the presence of high malpractice liability.

The data on legislative reforms come from Avraham's data (Avraham 2014). In the case of punitive damages, we utilize only legislative changes that apply to products liability. Since Avraham's data focus primarily on medical malpractice litigation, we supplemented these data with our own search using state statutes to determine the rules governing products liability.

Table 2 describes the legislative changes that occurred during the timing of our study sample. During our sample period six states (AL, AK, AR, ID, MS, MO, and OH) adopted punitive damage caps that applied to products liability cases, while two states (PA and IL) repealed caps. During this same time period, 8 states (FL, GA, IL, MS, NV, OH, OK, TX) adopted non-economic caps for medical malpractice cases.

3. Drug characteristics

In our regression analyses, we control for other characteristics of drugs that could relate to sales. These include the generic status of the drug, as well as the number of generic competitors within the same therapeutic class. We use the 2007 Red Book²⁰ to provide information on generic status and therapeutic class by drug. Broadly speaking, the therapeutic class is a means for grouping drugs according to their use in clinical settings (e.g., "beta blockers"). Our data included 74 different therapeutic categories.²¹ To construct the number of generic competitors, we sum across drugs within class for all the drugs in our sample by year.

While generic drugs are older on average, the age of a drug could have an independent effect on demand. Older drugs have more established track records of real-world use, potentially generating more information on safety or real-world efficacy that cannot be gleaned from clinical trials of a few thousand patients. We use information on a drug's age, defined as current year minus the year of approval, which we obtain from the Food and Drug Administration's (FDA) Orange Book database.

Finally, we also use information on black box warnings on the package inserts of prescription drugs. "Black box warnings" represent official disclosures from the manufacturer of adverse event risks.

¹⁹ We focus on noneconomic damage caps because these reforms are generally found to have the strongest and most robust impact on expected liability Danzon, P. M. and L. A. Lillard (1983). "Settlement out of court: The disposition of medical malpractice claims." <u>Journal of Legal Studies</u> **12**: 345-377, Danzon, P. M. (1986). "The Frequency and Severity of Medical Malpractice Claims: New Evidence." <u>Law and Contemporary Problems</u> **49**(2): 57-84, Sloan, F. A., P. M. Mergenhagen, et al. (1989). "Effects of tort reforms on the value of closed medical malpractice claims: A microanalysis." <u>Journal of Health, Politics, Policy and Law</u> **14**(4): 663-689..

²⁰ The Red Book™ is a database on pharmaceutical produces published by Truven Health Analytics that includes a comprehensive set of identifiers on all brand, generic and over-the-counter products.

²¹ This includes a category in which we pooled together relatively rare drugs where there were insufficient observations to include class fixed effects separately (about 5% of drugs fell in this category).

If manufacturers disclose safety risks in the form of trial or other data, the FDA may choose to require the issuance of a black box warning for the drug. Data on black box warnings were gathered by hand from archived MedWatch reports available on the FDA website. Our black box warning data cover the warnings in effect between 1996 and 2009.

Table 3 summarizes the quantity and other drug utilization statistics. In total, we have data on up to 1,227 drugs for up to 10 years in 50 states and the District of Columbia. Since some drugs are introduced or withdrawn from the market during the sample, we end up with 510,969 observations (approximately 8 years per drug per state). There are about 1.8 prescriptions per 1,000 visits on average, with an average price per prescription of about \$198. The share of observations with high products liability and high malpractice liability is almost the same, about 60%, but this masks considerable variation across states. About 22% and 24% of observations are states and years with only high products liability or malpractice liability, respectively, and 36% of observations have both.

4. Products liability and medical malpractice liability

We employ data on actual liability payments by drug manufacturers and physicians, in order to investigate how our tort policy variables affect upstream versus downstream liability. We gathered data on drug litigation from the LexisNexis book *Guide to Drugs in Litigation*. This book, commonly referred to as the "Grey Book," is updated annually and covers all drug suits in LexisNexis's extensive database of litigated cases. Like all publicly available litigation data, its sample frame is limited to cases that go to trial and generate a written opinion and/or trials and settlements discussed in other public sources.

Our data on physician malpractice liability payments come from the National Practitioner Data Base (NPDB). The NPDB is a nationwide database of payments in malpractice cases and includes payments that result from settlements and plaintiff wins at trial. The database contains information on over 200,000 medical malpractice payments made on behalf of practitioners in all 50 states and the District of Columbia.²² We aggregate these data to the state-year level. We employ data from the period 1992 to 2007 in our analysis.²³ One limitation of the NPDB is that it does not contain dropped cases. Ideally we would like to capture the full cost of litigation to doctors, which would include the time and reputation costs of dealing with all cases even those which are eventually dropped (Seabury, Chandra et al. 2013). This limitation is arguably less important in our application since doctors are typically named in lawsuits against pharmaceutical companies and then given a reduced settlement or

-

These data have been used for research many times and are discussed in more detail elsewhere Chandra, A., S. Nundy, et al. (2005). "The growth of physician medical malpractice payments: evidence from the National Practitioner Data Bank." Health Aff (Millwood) **Suppl Web Exclusives**: W5-240-W245-249, Helland, E., J. Klick, et al. (2005). "Data watch: Tort-uring the data." Journal of Economic Perspectives: 207-220, Helland, E. and G. Lee (2010). "Bargaining in the Shadow of the Website: Disclosure's Impact on Medical Malpractice Litigation." American law and economics review 12(2): 462-508..

The NPDB is the most comprehensive, publicly available database on malpractice claims, but also has some

The NPDB is the most comprehensive, publicly available database on malpractice claims, but also has some problems with incomplete reporting Government Accounting Office (2000). Major Improvements Are Needed to Enhance Data Bank's Reliability. Washington, DC, GAO.. However, for our purposes it is important to note that it is unlikely these reporting issues would be differentially affected across states or across types of claims (e.g., medication-related or other).

the case against the doctor is dropped in exchange for their testimony against the manufacturer. Since we are only capturing the reduction in payments by the physician, and not the increase in dropped cases, our estimates are biased toward zero.

A few well known caveats about the NPDB should be mentioned. First since the NPDB includes only paid claims it does not reflect physicians' liability from uncompensated claims (i.e. lost time and legal costs). As such our estimates of the impact of tort reform represent a lower bound on changes in physician risk, because legal reforms may also reduce the incentive to file cases in the first place. The second is that we utilize information on medication error cases in determining the impact of punitive damage caps on physician liability. Not all of these cases involve "failure to warn" since the category would include cases involving known drug interactions, prescribing the wrong medication or the wrong dose. Nonetheless "failure to warn" cases would fall into this category. As such our results will again be biased toward zero since there is no reason to think that punitive damage caps should increase physician liability in cases that do not involve a pharmaceutical company.

C. Background on products liability and punitive damages for pharmaceutical manufacturers

1. Failure-to-warn liability in pharmaceuticals

Drug companies are exposed to products liability primarily through failure to warn suits, which subject companies to damages if they fail to disclose to physicians all drug side effects about which they should have known. Drug companies are not subject to design defect liability, because courts believe that drugs are inherently unsafe and companies cannot reformulate them to eliminate side effects (Restatement (Second) of Torts, §402A, comment K). Drug companies occasionally face liability for defects that arise during the manufacturing of a drug. Such cases are not thought to create significant liability, however, because the Food and Drug Administration (FDA) regulates companies' manufacturing processes, reducing the frequency of manufacturing defects.²⁴

There are several indications that products liability is an important cost of production for pharmaceutical manufacturers. Products liability is a primary driver of the pharmaceutical industry's legal liabilities (Viscusi 1991). In Table 4, we summarize information from the LexisNexis Drugs in Litigation reports (the so-called "Grey Book") from 1990-2009. We abstracted data from 665 trials. The average award in this sample was \$6.49 million. When a damage award was granted, the average award was \$15.85 million (approximately 41% of cases involved a damage award). Note that these numbers reflect only a fraction of the total costs of products liability to pharmaceutical manufacturers, as the vast majority are paid in out-of-court settlements and are not included in these figures. Also note that, in contrast to doctors, who purchase liability insurance against medical malpractice cases, drug companies are typically self-insured against products liability.

_

²⁴ For our empirical analysis, our predictions about the impact of liability on the quantity of drugs sales will be the same regardless of whether the source of liability is from failure to warn or manufacturing defects, though the predictions about the impact on safety could differ.

2. Sharing of liability between physicians and manufacturers

We rely on the idea that punitive damage caps lower the share of liability faced by upstream manufacturers. The crux of our argument relies on the position of a physician in drug safety litigation. In particular, when drug manufacturers face greater liability, they are more attractive targets for litigation, and it is more valuable to secure the cooperation of a physician to testify against the manufacturer. As such, punitive damage caps reduce the absolute liability faced by upstream manufacturers and make it less likely that doctors will be able to avoid liability themselves. In this manner, they reduce both the level and share of liability faced by manufacturers. We first flesh out the institutional details that underlie this argument and then substantiate it empirically.

Although punitive damages are relatively uncommon, they are frequently responsible for the largest verdicts in products liability (Eisenberg, Hannaford-Agor et al. 2006), and they are an important source of liability in failure-to-warn suits against pharmaceuticals. Table 4 shows that \$1.37 million (21%) of the average award in all pharmaceutical products liability cases were for punitive damages. Punitive damages are only granted in 4% of cases and 11% of cases with an award, but when they are granted, they average \$43 million.

Doctors and pharmaceutical manufacturers share liability in failure-to-warn drug cases for several reasons. First, the doctor's presence as a defendant allows plaintiffs to sue in state court. The doctor is local, but the drug company is often out of state. Therefore, suing the company directly would give rise to diversity jurisdiction and move the case to federal court (Willig 1985). Second, a failure to warn case hinges on doctor's testimony. Because the doctor is a so-called "learned intermediary," the adequacy of the warning depends on what the doctor knew rather than what the patient knew. If the doctor is named as a defendant, his or her best strategy is fairly clear: The doctor will argue that the drug's warning was not sufficiently clear to prevent injury. This would absolve the doctor of responsibility, but would make liability more likely for the drug manufacturer.²⁵

These conflicting defenses set up a possible commonality of interest between doctors and plaintiff's attorneys in cases involving pharmaceuticals. A doctor's liability for malpractice is effectively capped at their insurance policy limit (usually \$1 million or less for a specific incident). Thus, compensatory damages are close to the maximum that a plaintiff can get from individual doctor. Moreover, winning any amount for a doctor is very difficult and costly. Approximately 80% of malpractice claims against physicians result in no payment for a plaintiff (Jena, Seabury et al. 2011). ²⁶ In

²⁵ For example, a doctor could argue that the manufactures promotion was unclear about risk or not mentioned by drug reps. It has long been established drug companies have a duty to warn of potential adverse reactions in detailing see *Yarrow v. Sterling Drug, Inc.* 263 F. Supp. 159 (D.C.S.D. 1967).

²⁶ Despite this, physicians still report high levels of fear and anxiety over malpractice liability risk Carrier, E. R., J. D. Reschovsky, et al. (2013). "High physician concern about malpractice risk predicts more aggressive diagnostic testing in office-based practice." <u>Health affairs</u> **32**(8): 1383-1391., possibly because of the long and costly process for resolving a claim irrespective of outcome Seabury, S. A., A. Chandra, et al. (2013). "On Average, Physicians Spend Nearly 11 Percent Of Their 40-Year Careers With An Open, Unresolved Malpractice Claim." <u>Health Affairs</u> **32**(1): 111-119..

addition, the doctor's testimony is often required to be able to win punitive damages (Willig 1985). Thus the most direct path to success in a pharmaceutical product liability cases is to either to let the doctor out of liability altogether in exchange for testimony or to reduce the portion of the compensatory and non-economic damages the doctor must pay in the settlement.²⁷ This argument appears to be confirmed by our review of the Grey Book data, where 56% of cases involved a doctor named as a codefendant (Table 4). Focusing on the subset of cases that break out total payments into portions paid by doctors and pharmaceutical companies, doctors typically settle for very small amounts and often no payment at all.

Further evidence for the importance of doctors' testimony in products liability cases comes from the silicone breast implant cases of the 1990s and early 2000s. Following Surgeon General Kessler's 1992 decision to withdraw implants from the market, the already substantial volume of litigation picked up dramatically and did not abate until the mid-2000s (Hersch 2002; Viscusi 2007). Much like pharmaceutical litigation, medical device litigation requires doctors' testimony to successfully prosecute a case (Tancredi and Nelkin 2010). We examined data on 6,095 closed medical malpractice claims against plastic surgeons from a single, large, nationwide malpractice insurer from 1991-2005. Within these claims, 1,648 (27%) involved breast implants. For the claims that did not involve an implant, approximately 11.5% involve some kind of indemnity payment to the plaintiff. This was comparable to other surgical fields, in which the payment rate is 10.9%. However, just 5.4% of claims that involve an implant also result in physician payment to the plaintiff. If we further restrict the sample to cases involving ruptured implants (about 8%), the physician payment rate is just 1.2%.

In our empirical tests, we use punitive damage caps as exogenous shocks to manufacturer liability that (1) reduce the expected liability of manufacturers and (2) transfer that liability to increase the expected liability for physicians. For this approach to be reasonable, we need to establish that punitive damage caps indeed result in both these effects. The impact of punitive damages caps on expected products liability is relatively straightforward to see. For example, in 2005 a jury in Texas found Merck & Co. liable for a the death of a man who took the painkiller Vioxx and awarded his widow more than \$250 million, the vast majority of which came from punitive damages.³⁰ However, even at the time at which the verdict was awarded, it was widely understood that the plaintiff would be able to receive no more than \$26 million, because of the presence of a cap on punitive damages in Texas. Because

-

²⁷ Deals in which the plaintiff and a defendant reach a secret agreement to reduce one defendants damages at the expense of another are so common that there name for them in product liability. They are called Mary Carter agreements after the defendant in the case *Booth v. Mary Carter Paint Co.* 226 Cal. App. 2 d 8 (Fla. Dist. Ct. App. 1967.) Typically in drug cases the doctor remains a defendant to avoid diversity and testifies as an adverse witness without admitting personal liability.

²⁸ For a more detailed description of these data see Jena et al. Jena, A. B., S. Seabury, et al. (2011). "Malpractice risk according to physician specialty." <u>New England Journal of Medicine</u> **365**(7): 629-636. or Seabury et al. Seabury, S. A., A. Chandra, et al. (2013). "On Average, Physicians Spend Nearly 11 Percent Of Their 40-Year Careers With An Open, Unresolved Malpractice Claim." Health Affairs **32**(1): 111-119..

²⁹ We identify these with a text search of whether "implant" appears in the claim description field. Our results are essentially the same if we replace "implant" with "silicone" in the text search.

³⁰ See http://www.nbcnews.com/id/9006921/#.Up5B 8RDuSo, accessed December 1, 2013.

punitive damage awards represent a significant share of the large "blockbuster awards," and the threat of these can be important tools for settlement negotiations, caps on punitive damages likely have an impact on expected liability far beyond just their direct effect on verdict awards.³¹

Moreover, the data suggest that punitive damage caps divert liability away from manufacturers and on to doctors. Using malpractice awards data from the NPDB, we can empirically test this hypothesis that punitive damage caps shift liability from the manufacturer to the physician. Let D_{pijt} represent the malpractice damage award in case p that occurred in state i that involved an alleged error type j in year t. For our purposes, the key distinction is between damage awards for cases with medication error, as opposed to other types of medical errors. We estimate the regression model:

$$D_{pijt} = \alpha_i + \alpha_j + \alpha_t + \theta_U L^U_{it} + \theta_D L^D_{it} + \theta_{Uj} \alpha_j \times L^U_{it} + \alpha_X X_{it} + \epsilon_{pijt}$$

The policy variables are the tort rules L_{it} in state i at time t. We consider separate tort rules that impact the upstream manufacturer (L^U), the downstream physician (L^D) and the interaction between the two ($L^U \times L^D$). Heuristically, these can be interpreted as "high products liability," "high malpractice liability" and "high products liability and high malpractice liability," respectively. Specifically, "high products liability" is the absence of punitive damage caps, and "high malpractice liability" is the absence of noneconomic damage caps.

We also included several additional controls for state laws. Specifically we include whether the state has a split recovery for punitive damages, whether the state has modified the collateral source rule so that payments from third parties are deducted from any award, whether punitive awards have a higher evidence standard, whether tort awards are must be paid out periodically over multiple years rather than as a lump sum, whether the state has capped contingent fees, whether the state has limited joint and several liability and finally whether the state has a patient compensation fund that pays a portion of any award. In contrast to non-economic damage caps that directly limit physician liability by statute and punitive damage caps that primarily limit products liability awards we do not have strong priors on whether these limitations have a larger upstream or downstream impact and hence they are included only as controls.

Our goal is to test the hypothesis that punitive damage caps increase the damage awards paid by physicians only in cases involving medication errors. Defining medication error cases as type j=d, the most direct implication of this hypothesis is that $\theta_{Ud}<0$. We also expect that punitive damage caps should have no effect on awards for other types of cases, or $\theta_U=0$. Finally, we expect that noneconomic damage caps will lower physician damage awards, or $\theta_D>0$.

_

³¹ Some of the effect of caps on damage awards could be muted if they simply supersede adjustments that would be made anyway (e.g., reductions on appeal). Nevertheless, appeals are time consuming and costly, so even a reduction that occurs sooner will result in lower expected costs.

The regression model includes fixed effects for state, error type and year, as well as a vector X of other characteristics of the state in which the case occurred (including the fraction male, the fraction nonwhite, income per capita and the share of the population in 5-year age ranges).

Results of this regression are reported in Table 5. The first two rows report the effects of noneconomic damage caps and punitive damage caps, respectively, on the log malpractice payment per case, where malpractice payments data are taken from the NPDB. The third row reports the interaction term between products liability and cases involving medication errors.

As expected, we find that noneconomic damage caps (lower malpractice liability regimes) are associated with lower average payments across all specifications. The impacts range from a 6% reduction when controls are included to a 12% reduction when state, year and malpractice type fixed effects are included. Our findings also confirm that punitive damage caps (lower products liability regimes) have no direct effect on medical malpractice liability. However, when we focus on cases involving medication errors, punitive damage caps (lower upstream liability) increases damages paid by physicians by 13-14%. These results are consistent with our argument that punitive damage caps shift liability from upstream manufacturers to downstream physicians.

D. Empirical strategy

We test the effects of state liability rules using a difference-in-difference design that compares drug sales in a state that changes liability rules from year t to t+1 to a state that does not change during that span. Let Y_{gict} represent the sales of drug g in state i in year t, where drug g is a member of therapeutic class c. Our regression specification is

$$Y_{gcit} = \gamma_g + \gamma_i + \gamma_t + \beta_U L^U_{it} + \beta_D L^D_{it} + \beta_{UD} L^U \times L^D_{it} + \gamma_M M_{ct} + \gamma_G G_{ct} + \gamma_X X_{gct} + \epsilon_{igct}$$
 (2)

The regression includes fixed effects for drug (γ_g) , state (γ_i) , and year (γ_t) . The treatment variable is the tort rule L_{it} in state i at time t. We consider separate tort rules that impact the upstream manufacturer (L^U) , the downstream physician (L^D) and the interaction between the two $(L^U \times L^D)$. These can be interpreted as "high products liability," "high malpractice liability" and "high products liability and high malpractice liability," respectively.

The coefficients β_U , β_D and β_{UD} represent our test of the model of liability with vertical production. From the theory, we expect that high malpractice liability should reduce sales, because prescriptions subject physicians to liability risk (so $\beta_D < 0$). We expect that high products liability should increase sales because it shields physicians from liability and removes the disincentives against prescribing (so $\beta_U > 0$). Finally, we expect that this shielding effect of products liability should be strongest when physicians are subjected to the most risk (so $\beta_{UD} > 0$). Absent the liability spillovers from vertical production, we might still expect high malpractice liability to lower sales if drugs are considered potentially risky products, but we would not expect to find positive effects of products liability. If anything, absent the liability spillovers we would expect higher products liability to reduce sales by increasing costs.

It might also be true that "failure-to-warn" liability risk is mechanically higher, when manufacturers have indeed failed to warn. As a result, it is plausible that drugs with a greater share of disclosed safety risks will face more muted effects of liability rules on liability risk and on output. We test this hypothesis by stratifying our estimates for drugs with and without black box warnings, which represent officially disclosed safety risks. We then estimate β_{IJ} , β_{D} and β_{IJD} separately in both samples.

In addition to the fixed effects and liability indicators, our empirical model controls for the effect of competition by including the number of branded competitor drugs (M_{ct}) and the number of generic competitor drugs (G_{ct}) in the same therapeutic class c. Note that drugs are nested within classes, so we do not include separate fixed effects for class. Finally, the regression equation includes various controls X_{act} to address measurement issues and potential confounders.

Our liability shocks occur at the state level, so it is important to allow for correlation in the error terms across states (i.e., clustering). However, we also observe the same drug across states and years, and it is unlikely that the error terms are independent across drugs. Therefore, we estimate standard errors using the two-part clustering approach of Cameron, Gelbach and Miller (2011) to allow for clustering across states and therapeutic classes. Because drugs are nested within class, this approach allowed for a more flexible combination of possible correlations.

An important identifying assumption for this approach to provide valid estimates is that the adoption of tort reform is exogenous with respect to the pharmaceutical market in a state. This concern is mitigated by a free-rider problem across states. Since drugs are sold on a national market, any given state has a very limited impact on the profitability of a product, so producers have less incentive to invest lobbying efforts in that state. Moreover, since the punitive damage caps tend to affect all cases, these are more likely to be driven by general business interests than solely pharmaceuticals.

To strengthen our confidence that treatment variables are exogenous, we conduct two sets of validity tests. First we conduct a quasi-balancing test that compares adoption of damages caps across states by various outcome variables measured in the first year of the sample, 1997. The states are first binned into quintiles based on prescriptions per outpatient visit, total number of prescriptions, mean drug price, or outpatient visits in 1997. Then the figure plots the number of states with punitive and non-economic damages caps in each quintile. The findings of these tests are reported in Figure 1. Each outcome variable is reported in a separate panel. Importantly, we find no obvious monotonic pattern in adoption of either cap by any outcome measure. Using Wilcox rank-sum tests, we fail to reject the equality of the distribution of the number of adoptions of either punitive or noneconomic damage caps across quintiles for any of the outcome measures.

Our second validity check is to test for the presence of pre-existing trends in drug sales leading up to the adoption of either punitive or noneconomic damage caps (or both together). Specifically, we estimate Equation 3 including policy leads of 1, 2 and 3 years prior to the change in policies. If changes in the pharmaceutical market are driving the adoption of tort reform, we would expect to see significant effects in the pre-period of magnitudes similar to our "post-period" coefficients of interest. The results

of this test are discussed below in Section E, but we note here that we find no evidence of pre-existing trends.

E. Results

Table 1 presented raw descriptive statistics consistent with our model. Namely, the table shows that prescriptions rise with higher upstream liability for states in which liability is shared across physicians and drug manufacturers. Table 6 presents the analogous regression results, which are consistent with the raw data. As before, the top two rows in panel A report the direct effect of products liability and malpractice liability, respectively, and the third row represents the interaction effect, which is predicted to be positive. The direct effect of products liability is statistically insignificant, while the direct effect of higher malpractice liability is to lower drug sales by 15-19%. This is consistent with the prediction that global drug manufacturers will not materially respond to changes in one state's laws, even though physicians will.

The interaction effects are positive and significant, as predicted. Panel B aids in the interpretation of these by reporting the predicted change in prescribing behavior that would result from higher products liability, stratified by states with low and high malpractice liability. When malpractice liability is low, higher products liability has no statistically significant effect on prescriptions, consistent with the heterogeneous legal environment model. However, higher products liability boosts drug utilization by over 20% in states where physicians share liability.

In Table 7A and 7B we report the findings stratified according to drugs with and without black box warnings. Table 7A reports the coefficient estimates (analogous to the top part of Table 6), and panels I and II report the estimates for drugs with and without a warning in place, respectively. Since drugs with black box warnings have already disclosed more of their health harms, more of the liability risk is already shifted downstream to doctors. Thus, increasing upstream liability should lead to more muted effects on quantity, because there is less upstream liability to shift onto doctors. This is roughly what we find. In Table 7A we note that the direct effect of products liability is small and insignificant among both sets of drugs. Malpractice liability reduces sales in both cases, but the effect is only significantly offset by increases in producer liability when there is no black box warning in place.

Table 7B shows that in our preferred specification (with state and drug fixed effects), high products liability is always associated with statistically insignificant effects on sales in states with low malpractice liability, as expected. In states with high malpractice liability, higher products liability boosts sales by 24.9% for drugs without a black box warning, but just 12.3% (which is also insignificant) for drugs with a black box warning.

In Table 8 we report the results of our validity check that tested for pre-existing trends in prescriptions prior to the adoption of reforms. Reporting results only for the preferred specification (with state and drug fixed effects), columns I, II and III report the estimated effects for high products liability, high malpractice liability and the interaction, respectively. The top row reports the main effect while the next rows report the 1, 2 and 3 year lags. These results confirm the basic findings and suggest no evidence of pre-existing trends. The lead variables are generally smaller in magnitude and

inconsistent in sign compared to the main effects, and none of them is statistically significant. This, combined with the findings reported in Figure 1, support the case for the exogeneity of our policy variables.

III. Conclusion

This paper examined the implications of different tort liability regimes on output in a market defined by vertical production. We show that vertical production spread out across multiple jurisdictions can lead to unintended consequences of higher products liability rules. Conventional wisdom holds that an increase in tort liability on the upstream firm will (weakly) reduce sales of a risky product and improve safety. The theory of vertical production across jurisdictions, however, predicts that higher upstream liability may actually shield downstream distributors from liability and increase their sales of a risky product.

We test this prediction in the pharmaceutical market, where drug manufacturers face product liability and physicians—who are essentially the downstream distributors of pharmaceutical products—face malpractice liability. The regulation of these two forms of liability differs substantially across jurisdiction. We find that liability on the upstream pharmaceutical company increases the quantity of drugs sold when liability is shared with physicians, but has no effect when downstream physicians are insulated from liability risk. In other words, higher products liability by a single jurisdiction never has its strictly intended consequence, and can even generate perverse unintended consequences.

From a normative perspective, we have shown that upstream firms that are national in scope should face the same tort regime as localized downstream firms. In this way, the theory makes a case for harmonized liability rules across jurisdictions. Indeed, it even suggests that individual states can move towards efficiency by aligning their rules with the global average liability rule. This provides some hope for improving the structure of the liability regime. That is, states that focus on the welfare of their own consumers, and that understand the efficiency issues outlined in this study, may have incentives to harmonize with the broader market.

In practice, the political economy of state liability reform encompasses more than just consumer welfare. There may be electoral incentives for individual states to "act tough" on large, upstream firms, or be friendly towards large upstream firms that are housed in their own states. A full analysis of these political economic incentives lies beyond the scope of this paper, but if significant, this would suggest the value of national tort liability rules that naturally harmonize rules across states. Even so, there may continue to be misalignment across countries, since many upstream firms – drug manufacturers included – operate in multiple national jurisdictions. This issue is somewhat mitigated though by the greater ability to price-discriminate across national borders in some cases, including that of the pharmaceutical industry.

Our study suggests the value of investigating how the interaction of multiple independent firms, operating across multiple independent jurisdictions, complicates the effectiveness of tort liability rules. Further research may investigate interactions across goods markets, where multiple risky goods are used to produce a given output. More research is also needed on how these considerations affect the

political economy of tort reform at the state and national level. A competitive, complex, and disintegrated economy appears to have important implications for how we study tort reform, and how the economic analysis of tort reform should continue to evolve.

References

- Avraham, R. (2014) "Database of State Tort Law Reforms (5th)." DOI: http://dx.doi.org/10.2139/ssrn.902711.
- Avraham, R. and M. Schanzenbach (2015). "The impact of tort reform on intensity of treatment: Evidence from heart patients." <u>Journal of health economics</u> **39**: 273-288.
- Bolton, P. and M. Dewatripont (2005). Contract theory, The MIT Press.
- Cameron, A. C., J. B. Gelbach, et al. (2011). "Robust Inference With Multiway Clustering." <u>Journal of Business and Economic Statistics</u> **29**(2).
- Carrier, E. R., J. D. Reschovsky, et al. (2013). "High physician concern about malpractice risk predicts more aggressive diagnostic testing in office-based practice." <u>Health affairs</u> **32**(8): 1383-1391.
- Chandra, A., S. Nundy, et al. (2005). "The growth of physician medical malpractice payments: evidence from the National Practitioner Data Bank." <u>Health Aff (Millwood)</u> **Suppl Web Exclusives**: W5-240-W245-249.
- Choi, A. H. and K. E. Spier (2014). "Should Consumers be Permitted to Waive Products Liability? Product Safety, Private Contracts, and Adverse Selection." <u>Journal of Law, Economics, and Organization</u> **30**(4): 734-766.
- Cotet, A. M. (2012). "The impact of noneconomic damages cap on health care delivery in hospitals." American law and economics review **14**(1): 192-234.
- Currie, J. and W. B. MacLeod (2008). "First Do No Harm? Tort Reform and Birth Outcomes." <u>Quarterly Journal of Economics</u> **123**(2): 795-830.
- Danzon, P. M. (1986). "The Frequency and Severity of Medical Malpractice Claims: New Evidence." <u>Law and Contemporary Problems</u> **49**(2): 57-84.
- Danzon, P. M. and L. A. Lillard (1983). "Settlement out of court: The disposition of medical malpractice claims." Journal of Legal Studies **12**: 345-377.
- Eisenberg, T., P. L. Hannaford-Agor, et al. (2006). "Juries, Judges, and Punitive Damages: Empirical Analyses Using the Civil Justice Survey of State Courts 1992, 1996, and 2001 Data." <u>Journal of Empirical Legal Studies</u> **3**(2): 263-295.
- Frakes, M. (2012). "Defensive Medicine and Obstetric Practices." <u>Journal of Empirical Legal Studies</u> **9**(3): 457-481.
- Frakes, M. (2013). "The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules." <u>American Economic Review</u> **103**(1): 257-276.
- Godager, G. and D. Wiesen (2013). "Profit or patients' health benefit? Exploring the heterogeneity in physician altruism." J Health Econ **32**(6): 1105-1116.
- Goldman, D. P., G. F. Joyce, et al. (2004). "Pharmacy benefits and the use of drugs by the chronically ill." JAMA **291**(19): 2344-2350.
- Goldman, D. P., G. F. Joyce, et al. (2006). "Benefit design and specialty drug use." <u>Health Aff (Millwood)</u> **25**(5): 1319-1331.
- Government Accounting Office (2000). Major Improvements Are Needed to Enhance Data Bank's Reliability. Washington, DC, GAO.
- Hay, B. and K. E. Spier (2005). "Manufacturer Liability for Harms Caused by Consumers to Others." <u>The American Economic Review</u> **95**(5): 1700-1711.
- Helland, E., J. Klick, et al. (2005). "Data watch: Tort-uring the data." <u>Journal of Economic Perspectives</u>: 207-220.
- Helland, E. and G. Lee (2010). "Bargaining in the Shadow of the Website: Disclosure's Impact on Medical Malpractice Litigation." <u>American law and economics review</u> **12**(2): 462-508.

- Helland, E. and M. H. Showalter (2009). "The Impact of Liability on the Physician Labor Market." <u>Journal</u> of Law & Economics **52**: 635-779.
- Helland, E. A. and A. Tabarrok (2012). "Product Liability and Moral Hazard: Evidence from General Aviation." <u>Journal of Law and Economics</u> **55**(3): 593-630.
- Hensler, D. R. (2000). Class action dilemmas: Pursuing public goals for private gain, Rand Corporation.
- Hersch, J. (2002). Breast Implants: Regulation, Litigation, and Science. <u>Regulation Through Litigation</u>. W. Viscusi, Brookings Institution Press: 142-182.
- Jena, A. B., S. Seabury, et al. (2011). "Malpractice risk according to physician specialty." <u>New England Journal of Medicine</u> **365**(7): 629-636.
- Joyce, G. F., J. J. Escarce, et al. (2002). "Employer drug benefit plans and spending on prescription drugs." <u>Jama</u> **288**(14): 1733-1739.
- Kessler, D. P., W. M. Sage, et al. (2005). "Impact of malpractice reforms on the supply of physician services." JAMA: The Journal of the American Medical Association **293**(21): 2618-2625.
- Klick, J. and T. Stratmann (2007). "Medical Malpractice Reform and Physicians in High-Risk Specialties." The Journal of Legal Studies **36**(S2): S121-S142.
- Kornhauser, L. A. and R. L. Revesz (1989). "Sharing damages among multiple tortfeasors." <u>Yale Law</u> Journal: 831-884.
- Kornhauser, L. A. and R. L. Revesz (1994). "Multidefendant settlements: The impact of joint and several liability." <u>The Journal of Legal Studies</u>: 41-76.
- Krauss, M. I. (2002). "Product Liability and Game Theory: One More Trip to the Choice-of-Law Well." <u>BYU</u> L. Rev.: 759.
- Lakdawalla, D. and W. Yin (2013). "Insurers' Negotiating Leverage and the External Effects of Medicare Part D." Review of Economics and Statistics(0).
- Landes, W. M. and R. A. Posner (1980). "Joint and multiple tortfeasors: An economic analysis." <u>The</u> Journal of Legal Studies: 517-555.
- Landes, W. M. and R. A. Posner (1985). "A Positive Economic Analysis of Products Liability." <u>The Journal</u> of Legal Studies **14**(3): 535-567.
- LaPensee, K. T. (2003). "Analysis of a prescription drug prior authorization program in a Medicaid health maintenance organization." J Manag Care Pharm **9**(1): 36-44.
- Legros, P. and S. A. Matthews (1993). "Efficient and Nearly-Efficient Partnerships." <u>The Review of Economic Studies</u> **60**(3): 599-611.
- Malani, A. and J. Reif (2013). Interpreting Pre-trends as Anticipation: Impact on Estimated Treatment Effects from Tort Reform.
- Matsa, D. A. (2007). "Does malpractice liability keep the doctor away? Evidence from tort reform damage caps." <u>The Journal of Legal Studies</u> **36**(S2): S143-S182.
- Mello, M. M., A. Chandra, et al. (2010). "National costs of the medical liability system." <u>Health Affairs</u> **29**(9): 1569-1577.
- Miceli, T. J. (1997). <u>Economics of the law: torts, contracts, property, litigation</u>. New York, Oxford University Press.
- Miceli, T. J. and K. Segerson (1991). "Joint liability in torts: Marginal and infra-marginal efficiency." <u>International Review of Law and Economics</u> **11**(3): 235-249.
- Oates, W. E. and R. M. Schwab (1988). "Economic competition among jurisdictions: efficiency enhancing or distortion inducing?" <u>Journal of public economics</u> **35**(3): 333-354.
- Pace, N. M., S. J. Carroll, et al. (2007). Insurance class actions in the United States. Santa Monica, CA, RAND Corporation.
- Polinsky, A. M. and W. P. Rogerson (1983). "Products Liability, Consumer Misperceptions, and Market Power." The Bell Journal of Economics **14**(2): 581-589.

- Polite, B., R. M. Conti, et al. (2015). "Reform of the Buy-and-Bill System for Outpatient Chemotherapy Care Is Inevitable: Perspectives from an Economist, a Realpolitik, and an Oncologist." <u>Am Soc</u> Clin Oncol Educ Book: e75-80.
- Prosser, W. L. (1960). "The Assault upon the Citadel (Strict Liability to the Consumer)." <u>The Yale Law Journal</u> **69**(7): 1099-1148.
- Schwartz, V. E. and C. Silverman (2009). "Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety." <u>Tul. L. Rev.</u> **84**: 1203.
- Seabury, S. A., A. Chandra, et al. (2013). "On Average, Physicians Spend Nearly 11 Percent Of Their 40-Year Careers With An Open, Unresolved Malpractice Claim." <u>Health Affairs</u> **32**(1): 111-119.
- Shepherd, J. (2012). "Products Liability and Economic Activity: An Empirical Analysis of Tort Reform's Impact on Businesses, Employment, and Production." Vanderbilt Law Review **forthcoming**.
- Sloan, F. A., P. M. Mergenhagen, et al. (1989). "Effects of tort reforms on the value of closed medical malpractice claims: A microanalysis." <u>Journal of Health, Politics, Policy and Law</u> **14**(4): 663-689.
- Spence, M. (1977). "Consumer misperceptions, product failure and producer liability." <u>The Review of</u> Economic Studies **44**(3): 561-572.
- Sturgis, R. W. (1995). <u>Tort Cost Trends: An International Perspective, 1995</u>, Tillinghast-Towers Perrin. Sykes, A. O. (1984). "The economics of vicarious liability." Yale Law Journal: 1231-1280.
- Tancredi, L. and D. Nelkin (2010). Medical malpractice and its effect on innovation. <u>The liability maze:</u> the impact of liability law on safety and innovation. P. W. Huber, Brookings Institution Press: 251-273.
- Towers Watson. (2010). "US Tort Cost Trends: 2010 Update." Retrieved March 5, 2013, from http://www.towerswatson.com/assets/pdf/3424/Towers-Watson-Tort-Report-1.pdf.
- Viscusi, W. K. (1991). "Product and occupational liability." The Journal of Economic Perspectives: 71-91.
- Viscusi, W. K. (2007). "Regulation of health, safety, and environmental risks." <u>Handbook of law and</u> economics **1**: 591-645.
- Willig, S. H. (1985). "Physicians, pharmacists, pharmaceutical manufacturers: Partners in patient care, partners in litigation." Mercer L. Rev. **37**: 755.

Tables

Table 1. Average quantity of prescription drugs filled per outpatient visit by producer and physician liability regime

	Products liability		
Physician malpractice liability	Low liability states	High liability states	Difference (%)
All states	1.804	1.845	+2.3%**
Low liability states	1.849	1.753	-5.2%**
High liability states	1.771	1.902	+7.4%**

Notes: Table reports the average number of prescriptions per 1,000 outpatient visits at the drug-state-year level for all 50 states plus DC from 1998-2007. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. A ** represents statistical significance at the 1% level or better.

Table 2. Adoption and repeal of punitive damage caps for products liability cases and noneconomic damage caps in medical malpractice cases by state (1997-2008)

	Law was adopted or implemented	Law was repealed or no longer in effect
Caps on punitive	AK (1998), AL (2000), AR (2003), ID	IL (1998), OH (1998)
damages	(2004), MO (2005), MS (2003), OH	
	(1997, 2005)	
Caps on non-	FL (2004), GA(2005), IL(2005), <i>ME</i>	AK (2006), IL (1998), MI (2004), OH
economic	(2000), MS (2003), NV (2005), OH	(1998), OR (2000)
damages	(1997), OH (2003), OK (2004), SC	
	(2005), TN (2005), TX (2004)	

Notes: Laws in italics apply to all tort cases; all other laws apply only to medical malpractice cases. These were compiled from McCullough, Campbell, and Lane LLP's Summary of United States Medical Malpractice Law, Ronen Avraham's Data Base of State Tort Law Reforms (1st Edition), the American Tort Reform Association Tort Reform Record (1st Edition), and state statutes.

Table 3. Summary statistics

Variable	Mean	Std. Dev.
Prescriptions per 1,000 outpatient visits	1.83	5.95
Fraction in high products liability state	0.59	0.49
Fraction in high malpractice liability state	0.60	0.49
Price per Prescription (\$s)	198	1,028
Fraction generic	0.36	0.48
Fraction with black box warning in place	0.11	0.32
Number of generic competitors in class	11.20	11.47
Number of branded competitors in class	47.57	30.34
Age of drug (years)	13.65	6.55
Number of drugs	mber of drugs 1,227	
Observations 510),969

Notes: Table reports means and standard deviations of selected variables. Observations are at the drug-state-year level. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place.

Table 4. Outcomes from pharmaceutical products liability trials, 1990-2009

Variable	Mean	Std. Dev.
Had punitive damages (fraction)		
- All cases	0.04	0.19
- Cases with award	0.11	0.31
Punitive damage award (2008 \$ millions)		
- All cases	1.37	14.05
- Cases with any damage award	3.18	21.05
- Cases with a punitive damage award	43.09	66.70
Compensatory award (2008 \$ millions)		
- All cases	5.16	47.94
- Cases with a compensatory damage award	12.64	74.43
Total award (2008 \$ millions)		
- All cases	6.49	50.91
- Cases with any damage award	15.85	78.68
Doctor named as defendant	0.56	0.50
Total number of trials	6	65

Notes: Data report outcomes of pharmaceutical products liability trials from the LexisNexis Drugs in Litigation (2008 edition) from 1990-2009. Data on award amounts mostly come from jury verdict awards in trials, which could have been adjusted on appeal or in settlement. Settlement amounts were unknown except in rare cases (N=121) and are not included in the award amounts.

Table 5. Effect of punitive and non-economic damages caps on medical malpractice payments

	(1)	(2)	(3)	(4)
Dependent Variable: Log of payments in r	nedical malpractic	e cases (2008 \$s	5)	
High malpractice liability	0.119**	0.0602*	0.118**	0.0595*
	(0.0357)	(0.0266)	(0.0356)	(0.0266)
High products liability	0.0159	0.0173	0.0242	0.0255
	(0.0384)	(0.0272)	(0.0373)	(0.0265)
High products liability*drug Cases			-0.142*	-0.141*
			(0.0615)	(0.0603)
Fixed Effects	State, year,	type of alleged i	malpractice	
State demographic variables	No	Yes	No	Yes
Observations	215,010	215,010	215,010	215,010
R-squared	0.110	0.111	0.110	0.111

Notes: Table reports results of an OLS regression of payment in a malpractice case on the liability environment and case features. Malpractice payment data are from National Practitioner Data Bank and span 1992-2007. Robust standard errors clustered at the state level are reported in parentheses. Punitive Cap is defined as state-years with a punitive damage cap in place; Noneconomic Cap is defined as state-years with a noneconomic damage cap in place. All regressions contain controls for state laws (see text). A **, *, or * indicates statistical significance at the 1%, 5% or 10% level, respectively.

Table 6. Regression estimates of the effects of products liability (upstream) and medical malpractice liability (downstream) rules on drug quantity

	(1)	(11)	(111)	
Dependent variable: Log number of prescriptions per outpatient visit				
A. Regression coefficients				
Direct effect of high products liability	0.0722	0.0713	0.0588	
	(0.0646)	(0.0648)	(0.0536)	
Direct effect of high malpractice liability	-0.189**	-0.186**	-0.153**	
	(0.0561)	(0.0569)	(0.0521)	
Interaction effect of high products	0.174**	0.173*	0.147*	
liability and high malpractice liability	(0.0669)	(0.0683)	(0.0620)	
B. Implied effects				
Effect of high products liability when	+7.2%	+7.1%	+5.9%	
malpractice liability is low				
Effect of high products liability when	+24.7%**	+24.4%**	+20.6%**	
malpractice liability is high				
Mean of dependent variable (levels)	1.83 prescriptions per 1,000 visits			
Fixed effects	Year,	Year, state,	Year, state,	
	state	ther. class	drug	
Other covariates	Generic status, black box warnings,		x warnings,	
	number of brand competitors,			
	number of generic competitors,			
	drug age, state demographics			

Notes: Table reports the results of regression of the number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Each column reports the results of a different regression based on the fixed effect structure included. Data are at the drug-state-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. A **, *, or + indicates statistical significance at the 1%, 5% or 10% level, respectively.

Table 7A. Regression coefficient estimates of the effects of state liability regimes on drug quantity stratified by the presence of a black box warning

	(1)	(11)	(III)	
Dependent variable: Log Number of Prescriptions per Outpatient Visit				
A. Drugs with a black box warning in place				
Direct effect of high products liability	0.0760+	0.0742	0.0701	
	(0.039)	(0.0576)	(0.0711)	
Direct effect of high malpractice liability	-0.123**	-0.118*	-0.109+	
	(0.0282)	(0.0509)	(0.0622)	
Interaction effect of high products	0.0712+	0.0655	0.0527	
liability and high malpractice liability	(0.036)	(0.0578)	(0.0754)	
B. Drugs without a black box warning in place	се			
Direct effect of high products liability	0.0662	0.0656	0.0544	
	(0.0623)	(0.0626)	(0.0540)	
Direct effect of high malpractice liability	-0.189**	-0.187**	-0.151**	
	(0.0549)	(0.0557)	(0.0509)	
Interaction effect of high products	0.185**	0.183**	0.155*	
liability and high malpractice liability	(0.0660)	(0.0673)	(0.0618)	
Fixed effects	Year, state	Year, state,	Year, state,	
		therapeutic	drug	
		class		
Other covariates	Generic status, black box warnings,			
	number of brand competitors,			
	number of generic competitors,			
	drug age, state demographics			

Notes: Table reports the results of regression of the log number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drug-state-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. A **, *, or + indicates statistical significance at the 1%, 5% or 10% level, respectively.

Table 7B. Implied effects of state liability regimes on drug quantity stratified by the presence of a black box warning

	(1)	(11)	(111)
Dependent variable: Log Number of Prescri	ptions per Outpa	tient Visit	
A. Drugs with a black box warning in place			
Mean of the dependent variable (levels)	1.78 pr	escriptions per 1,00	00 visits
Effect of high products liability when	+7.6% ⁺	+7.4%	+7.0%
malpractice liability is low			
Effect of high products liability when	+14.7%**	+14.0%+	+12.3%
malpractice liability is high			
B. Drugs without a black box warning in pla	псе		
Mean of the dependent variable (levels) 2.20 prescriptions per 1,000 visits			00 visits
Effect of high products liability when	+6.6%	+6.6%	+5.4%
malpractice liability is low			
Effect of high products liability when	+22.5%*	+25.1%**	+24.9%**
malpractice liability is high			
Fixed effects	Year, state	Year, state,	Year, state,
		therapeutic	drug
		class	
Other covariates	Generic status, black box warnings,		
	number of brand competitors,		
	number of generic competitors,		
	drug	age, state demogra	phics

Notes: Table reports the results of regression of the log number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drug-state-year level. A **, *, or + indicates statistical significance at the 1%, 5% or 10% level, respectively. Variance estimates were computed to allow for two-level clustering within states and within therapeutic classes.

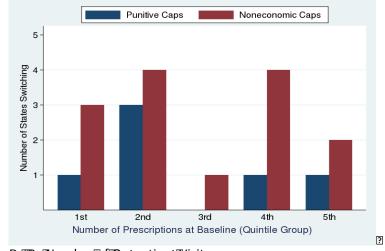
Table 8. Test for pre-existing trends in drug quantity leading changes in products liability or malpractice regimes

	(1)	(11)	(III)		
Dependent variable: Log Number of Prescriptions per Outpatient Visit					
	Direct effect of high products liability	Direct effect of high malpractice liability	Interaction effect of high products liability and high malpractice liability		
Direct effect of the policy	0.0820	-0.180*	0.197*		
	(0.0954)	(0.0726)	(0.0871)		
Policy Leads:					
- 1 year	-0.0594	0.0829	-0.121		
	(0.0916)	(0.0957)	(0.107)		
- 2 years	-0.0371	0.0716	-0.0946		
	(0.0795)	(0.0842)	(0.0937)		
- 3 years	0.0624	-0.0163	-0.0631		
	(0.162)	(0.0578)	(0.0871)		
Fixed effects	Year, state, drug				
	Gen	Generic status, black box warnings,			
Other covariates	number of brand competitors,				
	number of generic competitors,				
	d	rug age, state demo	graphics		

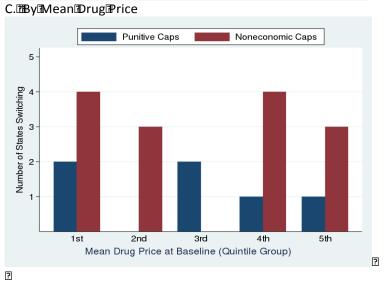
Notes: Table reports the results of regression of the number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drug-state-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. A **, *, or + indicates statistical significance at the 1%, 5% or 10% level, respectively.

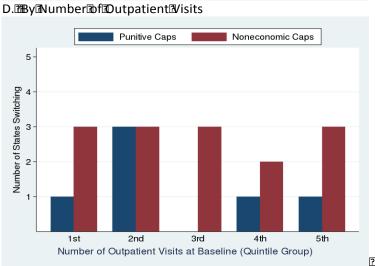
Figures

Figure 1. Distribution of changes in damages caps by state characteristics.



B. PBy Number of Prescriptions





Appendix

A. Proof of Proposition 2C

If the downstream firm makes correct inferences about safety from the upstream firm's disclosure, welfare in jurisdiction i is

$$W_i(x_i) = V_i(f(x_i)) - [c+h]x_i$$

 V_i is the value of the output to consumers in jurisdiction i. Welfare in the jurisdiction is equal to the value of output net of the true costs associated with the use of the hazardous input. Total welfare across all N jurisdictions is the sum of the above expression across all jurisdictions i. An increase in the upstream tort parameter in jurisdiction i has the following effect on welfare in jurisdiction i:

$$\frac{\partial W_i(x_i^{**})}{\partial a_i} = [V_i f'(x_i^{**}) - c - h] \frac{\partial x_i^{**}}{\partial a_i} \left(\frac{\partial a_i}{\partial t_i} + \frac{\partial a_i}{\partial r} \frac{\partial r^{**}}{\partial t_i} \right)$$

As explained in the text, the term in brackets is negative if $a_i > \bar{a}$ because that would imply $\bar{a}h + (1-a_i) < 1$ and the downstream firm does not internalize the full health costs of the upstream output. For the same reason it is positive if $a_i < \bar{a}$. The first term in parentheses $(\partial a_i/\partial t_i)$ is positive by assumption that increases in the tort parameter increase the share of liability upstream. The second term in parentheses is negative: higher upstream liability increases disclosure, which reduces upstream liability. It follows that the effect of a local increase in upstream liability is ambiguous.

Now consider what happens in the limit as $\Sigma_{\neg i} x_j \to \infty$. A local increase in upstream liability has no effect on upstream disclosure, i.e., $\lim \partial r^{**}/\partial t_i = 0$, so the term in parentheses becomes positive. Given that $\partial x^{**}/\partial a_i > 0$, it follows that the local welfare effect of a local increase in upstream liability is positive if $a_i < \overline{a}$ and negative otherwise.

The global welfare effect of a local increase in upstream liability is:

$$\Sigma_{j} \frac{\partial W_{j}(x_{j}^{**})}{\partial t_{i}} = \frac{\partial W_{i}(x_{i}^{**})}{\partial t_{i}} + \Sigma_{j \neq i} \left[V_{j} f'(x_{j}^{**}) - c - h \right] \frac{\partial x_{j}^{**}}{\partial a_{i}} \left(\frac{\partial a_{i}}{\partial r} \frac{\partial r^{**}}{\partial t_{i}} \right)$$

Unlike in the case of design and manufacturing defects, there is no spillover effect on safety in foreign jurisdictions because safety is assumed exogenous. Because the global effect is the local effect (first term) plus the non-local effect (the second term), the impact of a local increase in upstream liability is ambiguous. However, in the limit as $\Sigma_{\neg i} x_j \to \infty$, the non-local effect goes to zero because local liability rules cannot affect upstream disclosure. So the global welfare effect converges to the local welfare effect.

B. Proofs for Model with Upstream Monopolist

In this section, we extend and generalize our main results to an environment in which the upstream firm is a monopolist. For notational convenience, we derive our results for a homogeneous legal environment in which $t_i=t$. Heterogeneity produces results identical to those described in the text, but with additional notation.

Upstream firm. In this context, the hazardous good producer solves the following:

$$\max_{r,w} \Sigma_j x_j(r,w)(w-c-a(t,r)h)$$

Input demand falls in the degree of safety disclosures, so that $\frac{\partial x_i}{\partial r} < 0$, and it is downward-sloping, so that $\frac{\partial x_i}{\partial w} < 0$. Finally, note that the cross-partial between r and w is zero. All these results flow from the optimal input demand of the downstream firm. (As before, $\frac{\partial a}{\partial t} > 0$.)

This problem has the following first-order conditions:

$$\sum_{j} \frac{\partial x_{j}}{\partial w} (w - c - ah) + \sum_{j} x_{j} = 0$$

$$\sum_{i} \frac{\partial x_{j}}{\partial r} (w - c - ah) + \sum_{i} x_{j} (-a_{r}h) = 0$$

When t rises, the FOC for r rises, holding w fixed, indicating that r must go up. The price effect is offsetting, however, as the monopolist raises her price in response to the higher level of t. In the heterogeneous jurisdiction case, however, this effect is negligible. Therefore, an increase in the upstream tort parameter causes the upstream firm to disclose more risks: $\partial r/\partial t > 0$.

Downstream firm. The downstream firm in jurisdiction i solves the following problem:

$$\max_{\mathbf{x}_{i}} p_{i} f(x_{i}) - (w + \mathbf{E}[(1 - a(t_{i}, r^{**}))h|r^{**}h])x_{i}$$

where r^{**} is the upstream firm's equilibrium level of disclosure.

$$pf_x = w + E[(1-a)h|r^{**}h]$$

Note that the upstream firm's prices can be expressed as:

$$w = c + ah - \frac{\sum_{j} x_{j}}{\sum_{j} \frac{\partial x_{j}}{\partial w}}$$

Plugging this expression into the downstream firm's first-order condition yields:

$$pf_x = c + ah + E[(1-a)h|r^{**}h] - \frac{\sum_j x_j}{\sum_j \frac{\partial x_j}{\partial w}}$$

Provided that the downstream firm makes accurate inferences about expected harm, this simplifies to:

$$pf_x = c - \frac{\sum_j x_j}{\sum_j \frac{\partial x_j}{\partial w}}$$
 (3)

Just as in the competitive case, a change in upstream liability due to disclosure is perfectly offset by a reduction in downstream liability due to that disclosure. Although the downstream firm only observes the marginal harm rh that the upstream firm discloses, the upstream price passes on the costs associated with non-disclosed harms. Disclosure drops out of the marginal condition for input choice and the downstream firm faces the full marginal harm h from use of the hazardous input. Note that we are abstracting from the inefficiencies associated with monopoly pricing, which are unrelated to the tort regime per se.

The following proposition summarizes these findings.

Proposition A-1. Suppose the downstream firm has chosen interior values for the hazardous and safe inputs. In a homogenous legal environment, a change in tort parameters that increases upstream liability share α will have no effect on the downstream firm's use of the hazardous input x_i or its output y_i .

A remarkable byproduct of this result is that, in the context of vertical production, higher or lower tort liability and thus higher or lower disclosure has no effect on welfare.

Proposition A-2. Suppose the downstream firm has chosen interior values of the hazardous input. Suppose further that the downstream firm makes correct inferences about the risks of the hazardous input. In this case, the allocation of liability a across firms and tort rules (t^U, t^D) have no effect on welfare. The market is always at the first-best level of welfare.

This result rests critically on certain assumptions we have made. First and foremost, we examine a homogenous legal environment. In a heterogeneous legal environment, upstream liability is not perfectly passed on through price and thus changes in tort rules affect downstream input choice. Second, we have chosen a parameterization of upstream and downstream liability where the consumer is fully compensated for his or her injuries. A less demanding sufficient condition is that a dollar decrease in one firm's liability increases the other firm's liability by a dollar, even if the consumer is not fully compensated.

C. Description of claims data

The data include enrollment files, medical and pharmacy claims and health plan benefits, and span 1997 to 2007. Enrollment records allow us to track who is eligible for services as well as basic demographics (age, gender, three-digit zip code of residence, and relationship to sponsoring employee).

Pharmacy claims in the data include all outpatient pharmaceutical purchases. Each claim includes the type of drug, drug name, National Drug Code (NDC), dosage, days supplied, place of purchase (retail or mail-order), payments by patients and health plans, type of drug dispensed (generic, multi-source brand, single-source brand), type of pharmacy (retail, mail-order), and type (new/refill). The number of health plans contributing data varies each year, with more than 40 plans contributing in the last two years. Thus, there are 421 plan-years of data in the existing data set. About 44 percent of these plan-years (n=187) cover retiree benefits, so there is substantial representation of older Americans in the data. Plans also vary in the length of time they appear in the data. Currently, there are 28 plans with five or more years of data.

The data are also representative of all major plan types (health maintenance organizations, HMOs; preferred provider organizations, PPOs; point-of-service, POS, plans; and fee-for-service, FFS, plans) with members in all 50 states. In 2005, approximately 41 percent of the sample was enrolled in HMOs; 25 percent, in PPOs; 24 percent, in POS plans; and the remainder in FFS plans. Geographically, 43 percent of enrollees resided in the South, 32 percent in the North Central region, 14 percent in the West, and 11 percent in the Northeast.

In the claims data, pharmacy claims are coded by NDC, a unique product identifier created by the FDA. However, the same "drug" could be assigned multiple NDCs according to different strength, dose or differences in the packaging or labeling of the product. For example, a search of the drug Lipitor on the FDA website reveals more than 75 different NDC codes.³² We aggregate these claims to the drug level according to the active ingredient (also referred to as the molecule name or "generic name"). We linked the data by NDC code to the 2007 Redbook and aggregated all claims according to the active ingredient name by the state, year gender and age-category level. Of course, even after adjusting for the national representativeness of the sample, some of the variation in quantity across states and years could be driven by variation in the size of the population or the utilization of medical services. Thus, we also computed the number of outpatient visits—the encounter most likely to results in a prescription—for each state, year gender and age category in Ingenix. Using the weights constructed by comparing Ingenix enrollment to the CPS population, we constructed weighted averages of prescriptions per outpatient visit at the drug, state and year level.

_

³² See http://www.accessdata.fda.gov/scripts/cd<u>er/ndc/proprietaryname.cfm</u>, accessed on December 1, 2013.